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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/799,534

03/12/2004

Long Sheng Yu

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EXAMINER

ALTER, ALYSSA MARGO

ART UNIT

PAPER NUMBER

3762

MAIL DATE

DELIVERY MODE

04/12/2011

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/799,534	YU ET AL.	
	Examiner	Art Unit	
	ALYSSA M. ALTER	3762	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 04 January 2011.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1,3-6,8-10,12 and 14-17 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1,3-6,8-10,12 and 14-17 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 12 March 2004 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Response to Arguments

1. Applicant's arguments with respect to claims 1, 3-6, 8-10, 12 and 14-17 have been considered but are moot in view of the new grounds of rejection necessitated by amendment.

Claim Rejections - 35 USC § 102

2. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

3. Claims 1, 3, 5, 9 and 14 are rejected under 35 U.S.C. 102(b) as being anticipated by Jassawalla et al. (US 6,001,056). Jassawalla et al. discloses a ventricular assist device with a pump (pumping portion 14 depicted in figures 1 and 2), an inflow tube (valved segment 22 in figures 1 and 2), adapter sleeve (flexible segment 26, depicted in figures 1-2, as well as figures 4-5) and gripping member (stitch(es) 196 and 194, depicted in figure 5).

4. The inflow tube and the adapter sleeve together form the extended inflow tube. The adapter sleeve has a coupler fitting (coupling 182 in figure 4) for mating with the inflow tube (col. 5, lines 25-38). The gripping member (stitch 196) engage with the extended inflow tube and are coupled to the exterior surface of the tube (see figure 5).

5. As to claim 3, the ventricle assist device includes a sewing ring (depicted as 166 in figures 4-5). As depicted in figure 1, the cannula body (186 in figure 5) is inserted into the ventricular apex of the heart. Furthermore, since the gripping member (stitches) attach the exterior of the extended inflow tube to the sewing ring and the sewing ring is used to engage the ventricle of the heart, the sewing ring is "configured to attach said gripping members to a ventricular apex of a heart".

6. As to claim 5, Jassawalla et al. discloses a reinforcement cage (112 and 164 in figures 3 and 5 respectively) with the adapter sleeve. As such, the examiner considers the adapter sleeve to include the reinforcement cage. The reinforcement cage includes ribs 116 bridges 118 and axial spaces 120. Therefore, the axial spaces, or grooves, form perforations on the adapter sleeve that "separate the adapter sleeve".

7. As to claim 9, the examiner considers the inflow tube to have an "extendable end" since one of the ends is configured to be attached to the adapter and thus extended. Thus, since the adapter is added to the inflow tube, the inflow tube includes an extendable end.

8. As to claim 14, Jassawalla et al. discloses a reinforcement cage (112 and 164 in figures 3 and 5 respectively). "The reinforcement cage 112 includes a plurality of circumferentially formed ribs 116 joined at periodic locations by bridges 118. Although not shown well in FIG. 3, the bridges 118 are circumferentially offset from each other from rib-to-rib to enable the reinforcement cage 112 to be axially extended (this is better seen in the conduit segment of the present invention seen in perspective in FIG. 4). That is, the cage 112 is desirably formed of a resilient biocompatible material such as

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polypropylene, and axial elongation of the segment 100 is permitted by virtue of the ribs 116 bending to enlarge the axial spaces 120 therebetween”(col. 6, lines 4-14). Thus the reinforcement cage, which is attached to the adapter sleeve, permits the adapter sleeve to extend and contract. Therefore, the examiner considers the reinforcement cage to be the “adjustable attachment member configured to attach to the adapter sleeve”.

Claim Rejections - 35 USC § 103

9. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

10. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

11. Claims 4, 6, 8, 10, 12 and 15-17 are rejected under 35 U.S.C. 103(a) as being unpatentable over Jassawalla et al. (US 6,001,056). Jassawalla et al. discloses discloses the device substantially as claimed except for the adapter sleeve being titanium or ceramic material. It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the material used for the adapter sleeve, since such a modification of the material would provide the predictable results of providing sufficient structure while maintaining in-vivo biocompatibility. Furthermore, it

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has been held to be within the general skill of a worker in the art to select a known material on the basis of its suitability for the intended use as a matter of obvious design choice. *In re Leshin*, 125 USPQ 416 (See MPEP 2144.07)

12. As to claim 8, Jassawalla et al. discloses the claimed invention except for the inflow tube including the bent end. It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the inflow tube to include the bent end instead of the pump, since it has been held that rearranging parts of an invention involves only routine skill in the art. *In re Japikse*, 86 USPQ 70 (see MPEP 2144.04) Furthermore, such a modification would not alter the circulation of the blood but merely relocates the bent end from the pump to the end of the inflow tube that engages with the pump.

13. As to claim 10, Jassawalla et al. discloses the claimed invention except for the inflow tube including a rotatable end. It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the inflow tube to include the rotatable end instead of the adapter sleeve, since it has been held that rearranging parts of an invention involves only routine skill in the art. *In re Japikse*, 86 USPQ 70 (see MPEP 2144.04). Furthermore, such a modification would not substantially alter the engagement of the inflow tube and the adapter but merely changes which component has the coupler fitting.

14. As to claim 12, Jassawalla et al. discloses the reinforcement cage, which is attached to the adapter sleeve, permits the adapter sleeve to extend and contract (col. 6, lines 4-14). Therefore, the examiner considers the reinforcement cage to be the

“adjustable attachment member configured to attach to the adapter sleeve” (as stated above in reference to claim 14). Therefore, the modified Jassawalla et al., as applied to claim 4 above, discloses an adapter sleeve (segment 26) made of titanium with an attached adjustable attachment member (reinforcement cage 122).

15. As to claims 15-17, Jassawalla et al. discloses the device substantially as claimed except for the gripping members being gripping pins for engaging with cylindrical ring and spring ring. It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the gripping members of Jassawalla et al. to include gripping pins that engagement with cylindrical and spring rings in order to provide the predictable results of ensuring the adapter sleeve and reinforcement cage are sufficiently attached to the sewing ring of the ventricle assist device. Furthermore, such a modification to include pins enables proper positioning of the reinforcement cage on the ventricle assist device.

Conclusion

16. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the

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shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to ALYSSA M. ALTER whose telephone number is (571)272-4939. The examiner can normally be reached on M-F 8am to 4pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Niketa Patel can be reached on (571) 272-4156. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Alyssa M Alter/
Examiner
Art Unit 3762

/Niketa I. Patel/
Supervisory Patent Examiner, Art Unit 3762